Attorney's Docket No.: 18202-020001 / 1088

2-020001 / 1088

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Zhi, et al. Art Unit: 1625

Serial No.: 10/684,229 Examiner: Charanjit Aulakh

Filed : October 10, 2003 Cust. No. : 20985

Conf. No.: 8639

Title : 5-CYCLOALKENYL 5H-CHROMENO[3,4-f]QUINOLINE DERIVATIVES

AS SELECTIVE PROGESTERONE RECEPTOR MODULATOR

**COMPOUNDS** 

## Mail Stop Amendment

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

## TRANSMITTAL LETTER

Dear Sir:

Transmitted herewith are a Supplemental Information Disclosure Statement, Forms PTO-1449 (5 pages), copies of cited non US patent references, a check in the amount of \$180.00, and a return postcard for filing in connection with the above-identified application. Because this Supplemental Information Disclosure Statement is filed after the receipt of a first office action on the merits in the above-referenced application, a check for the filing fee of \$180.00 is enclosed. If it is determined that the fee amount is incorrect or if the check is missing, the Office is hereby authorized to charge the fee to Deposit Account No. 06-1050, as stated below:

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The Commissioner is hereby authorized to charge any fees that may be due in connection with this paper or with this application during its entire pendency to Deposit Account No. 06-1050. A duplicate of this sheet is enclosed.

Respectfully submitted,

Stephanie Seidman Reg. No. 33,779

**Dated: June 30, 2005** 

Attorney Docket No. 18202-020001/1088

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San Diego, California 92130 Telephone: (858) 678-5070 Facsimile: (202) 626-7796 email: seidman@fr.com

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# SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT IN ACCORDANCE WITH 37 C.F.R. §§ 1.97-1.98

Since this Supplemental Information Disclosure Statement is filed after the receipt of a First Office Action on the Merits for the above-captioned application, a check for the filing fee of \$180.00 is enclosed. If it is determined that the fee amount is incorrect or if the check is missing, the Office is hereby authorized to charge the fee to Deposit No. 06-1050.

In accordance with the duty of disclosure imposed by 37 C.F.R. §1.56 to inform the Patent Office of all information known by Applicant or Applicant's representative that may be material to the examination of the subject application, Applicant's representative hereby provides this Information Disclosure Statement that is prepared in accordance with 37 C.F.R. §§1.97-1.98. Forms PTO-1449 (5 pages) and copies of the cited non U.S. Patent documents are provided herewith.

All the documents cited on the Form PTO-1449 are in the English language. Hence, in accordance with the requirements of 37 C.F.R. §1.98, as amended effective March 16, 1992, no further explanation of the listed items is necessary.

07/05/2005 MBEYENE1 00000031 10684229

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Attorney's Docket No.: 18202-020001 / 1088

Applicant: Zhi, et al. Serial No.: 10/684,229 Filed: October 10, 2003

Supplemental Information Disclosure Statement

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Applicant also makes known to the Examiner the following pending U.S. and International Applications that have one or more common inventors and/or are commonly owned:

Docket No.	U.S.S.N.	Filed	Publ. No.
002007/1002F	08/141,246	10/22/93	n/a
002009/1002H	08/141,496	10/22/93	n/a
003014/1014N	10/739,933	12/17/03	n/a
004002/1026B	08/484,487	06/07/95	n/a
004003/1026C	10/847,732	05/17/04	20040209839
005003/1028C	10/360,580	02/05/03	20040019072
007002/1033B	09/277,405	03/26/99	n/a
009001/1042	08/883,115	06/26/97	n/a
013002/1062B	10/238,363	09/09/02	20030186970
014002/1066B	10/329,307	12/23/02	20030149268
015002/1073B	10/299,909	11/18/02	20030130505
017001/1081	10/080,926	02/22/02	20020183346
018001/1082	10/080,503	02/22/02	20020183314
020001/1088	10/684,229	10/10/03	20040152718
033001/1051	09/463,542	01/21/00	n/a
035002/1059B	10/229,649	08/27/02	20030013766
046003/1057C	09/866,025	05/25/01	n/a
048001/1087	10/684,212	10/10/03	20040152717
051001/1814	10/211,969	08/01/02	n/a
057001/1091	10/684,227	10/10/03	20040147530

Docket No.	Intl. No.	Filed	Publ. No.
022WO1/1096PC	PCT/US04/022907	07/16/04	2005/017185
023WO1/1097PC	PCT/US04/023788	07/16/04	2005/009104
024WO1/1098PC	PCT/US04/023093	07/16/04	2005/016255
026WO1/1100PC	PCT/US04/023010	07/16/04	2005/010202
027WO1/1110PC	PCT/US2005/06627	02/24/05	Awaiting
028WO1/1112PC	PCT/US2005/07867	3/11/05	Awaiting
030WO1/1111PC	PCT/US04/027483	08/23/04	2005/018573

Although these documents are made known to the Patent and Trademark Office in compliance with Applicant's duty of disclosure, such disclosure is not to be construed as an admission by Applicant or Applicant's representative that any of the references, singly or in any combination thereof, is effective as prior art against the subject application. In accordance with 37 C.F.R. §1.97(h), the filing of this Information Disclosure Statement shall

Applicant: Zhi, et al. Attorney's Docket No.: 18202-020001 / 1088

Serial No.: 10/684,229 : October 10, 2003

Supplemental Information Disclosure Statement

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not be construed to mean that a search has been made or that no other material information as defined in 37 C.F.R. §1.56(b) exists.

Applicant respectfully requests that the Examiner review the foregoing references and they be made of record in the file history of the above-captioned application.

Respectfully submitted,

Stephanie L. Seidman Reg. No. 33,779

**Dated: June 30, 2005** 

Attorney Docket No. 18202-020001 / 1088

Address all correspondence to:

Stephanie L. Seidman Fish & Richardson P.C. 12390 El Camino Real San Diego, California 92130 Telephone: (858) 678-5070

Facsimile: (202) 626-7796 email: seidman@fr.com

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Substitute Form PTO-1449 (Modified)

FRACE S. Department of Commerce
Patent and Trademark Office

Attorney's Docket No. 18202-020001/1088

Application No. 10/684,229

# List of Patents and Publications for Applicant's Information Disclosure Statement

Applicant Lin Zhi et al.

Filing Date

October 10, 2003

Group Art Unit 1625

(37 CFR §1.98(b))

- <u>-</u>				nt Documents			
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA	20030216388	11/20/03	Zhang et al.	514	230.5	03/12/03
	AB	20030220388	11/27/03	Fensome et al.	514	414	06/06/03
	AC	20030225109	12/04/03	Fensome et al.	514	256	04/22/03
·	AD	2004/0147530	10/10/03	Zhi et al.	514	256	10/10/03
	AE	20040152717	08/05/04	Zhi et al.	514	285	10/10/03
	AF	20040186101	09/23/04	Zhang et al.	514	230.5	01/29/04
	AG	5,506,102	04/09/96	McDonnell et al.	435	6	10/28/93
	AH	5,688,808	11/18/97	Jones et al.	514	285	06/05/95
	AI	5,688,810	11/18/97	Jones et al.	514	311	06/05/95
	AJ	5,696,130	12/09/97	Jones et al.	514	291	06/05/95
	AK	5,696,133	12/09/97	Jones et al.	514	314	06/05/95
	AL	5,808,139	09/15/98	Pathirana et al.	560	138	09/08/94
	AM	5,994,544	11/30/99	Jones et al.	546	62	10/08/97
	AN	6,001,846	07/25/00	Bender et al.	514	285	02/17/98
	AO	6,093,821	07/25/00	Jones et al.	544	333	10/08/97
	AP	6,093,825	07/25/00	Jones et al.	546	62	05/27/98
	AQ	6,093,826	07/25/00	Edwards et al.	546	62	06/08/98
	AR	6,121,450	09/19/00	Jones et al.	546	81	10/08/97
	AS	6,172,241	01/09/01	Edwards et al.	549	280	10/15/99
	AT	6,268,497	07/31/01	Edwards et al.	546	62	04/12/00
	AU	6,306,851	10/23/01	Santilli et al.	514	230.5	04/19/00
	AV	6,319,912	10/20/01	Grubb et al.	514	171	04/19/00
	AW	6,329,416	12/11/01	Grubb et al.	514	415	04/19/00
	AX	6,339,098	01/15/02	Collins et al.	514	373	04/19/00
	AY	6,355,648	03/12/02	Fensome et al.	514	275	04/19/00
	AZ	6,358,947	03/19/02	Zhi et al.	514	229.5	04/19/00
	BA	6,358,948	03/19/02	Zhang et al.	514	230.5	04/19/00

**Examiner Signature** 

Date Considered

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Substitute Form PTO-1449 U.S. Department of Commerce (Modified) Patent and Trademark Office					Application No. 10/684,229		
		d Publications n Disclosure S	for Applicant's tatement	Applicant Lin Zhi et al.	-		
(07.055.04.06				Filing Date October 10, 200	3	Group Art Uni 1625	t
(37 CFR §1.98	3(0))		U.S. Pater	nt Documents		1023	
Examiner Initial	Desig.	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	BB	6,369,056	04/09/02	Zhang et al.	514	230.5	04/19/00
	BC	6,380,178	04/30/02	Grubb et al.	514	171	04/19/00
	BD	6,380,207	04/30/02	Coghlan et al.	514	285	02/13/98
	BE	6,380,235	04/30/02	Zhang et al.	514	395	04/19/00
	BF	6,391,907	05/21/02	Fensome et al.	514	409	04/19/00
	BG	6,399,593	06/04/02	Grubb et al.	514	171	04/19/00
	вн	6,407,101	06/18/02	Collins et al.	514	230.5	04/19/00
	BI	6,417,214	07/09/02	Ullrich et al.	514	378	04/19/00
=-	BJ	6,436,929	08/20/02	Zhang et al.	514	230.5	04/19/00
	BK	6,441,019	08/27/02	Santilli et al.	514	409	07/17/01
	BL	6,444,668	09/03/02	Grubb et al.	514	230.5	04/19/00
	ВМ	6,448,405	09/10/02	Jones et al.	546	62	10/08/97
	BN	6,462,032	10/08/02	Grubb et al.	514	171	04/19/00
	во	6,498,154	12/24/02	Grubb et al.	514	171	04/19/00
	BP	6,503,939	01/07/03	Grubb et al.	514	415	10/15/01
	BQ	6,506,766	01/14/03	Coghlan et al.	514	285	07/05/00
	BR	6,509,334	01/21/03	Zhang et al.	514	230.5	04/19/00
	BS	6,521,657	02/18/03	Fensome et al.	514	414	10/30/01
	ВТ	6,544,970	04/08/03	Grubb et al.	514	171	05/22/02
	BU	6,566,358	05/20/03	Zhang et al.	514	230.5	09/06/01
	BV	6,566,372	05/20/03	Zhi et al.	514	312	08/24/00
	BW	6,583,145	06/24/03	Fensome et al.	514	256	09/24/02
	BX	6,608,068	08/19/03	Fensome et al.	514	256	12/11/01
	BY	6,693,103	02/17/04	Zhang et al.	514	256	12/17/01
	BZ	6,696,459	02/24/04	Jones et al.	514	285	10/14/97
	CA	6,713,478	03/30/04	Zhang et al.	514	230.5	03/12/03
	СВ	6,759,408	07/06/04	Grubb et al.	514	230.5	05/09/02

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Substitute Form PTO-1449  (Modified)  U.S. Department of Cor Patent and Trademar					Application No 10/684,22			
List of Patents and Publications for Applicant's Information Disclosure Statement				Applicant Lin Zhi et al.				
(37 CFR §1.98	(37 CFR §1.98(b))				Filing Date Group Art Unit October 10, 2003 1625		t	
			U.S. Pater	nt Documents				
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate	
	CC	6,794,373	09/21/04	Grubb et al.	514	171	03/01/02	
	CD	6,835,744	12/28/04	Ullrich et al.	514	409	04/24/02	
	CE	6,841,568	01/11/05	Fensome et al.	514	415	04/22/03	

	Foreig	n Patent Do	cuments or P	ublished Foreign	Patent A	Application	าร	
Examiner	Desig.	Document	Publication	Country or			Trans	lation
Initial	ID	Number	Date	Patent Office	Class	Subclass	Yes	No
	CF	0066103	11/09/00	PCT				
	CG	0066163	11/09/00	PCT				
	СН	0066164	11/09/00	PCT				
	CI	0066165	11/09/00	PCT				
	CJ	0066166	11/09/00	PCT				
	CK	0066167	11/09/00	PCT				
	CL	0066168	11/09/00	PCT				
	CM	0066225	11/09/00	PCT				
	CN	0066554	11/09/00	PCT				
	СО	0066555	11/09/00	PCT				
	СР	0066556	11/09/00	PCT				
	CQ	0066560	11/09/00	PCT				
	CR	0066564	11/09/00	PCT				
	CS	0066570	11/09/00	PCT				•
	CT	0066571	11/09/00	PCT				
	CU	0066574	11/09/00	PCT				
	CV	0066581	11/09/00	PCT			•	
	CW	0066590	11/09/00	PCT				,
	СХ	0066591	11/09/00	PCT				
·	CY	0066592	11/09/00	PCT				
	CZ	0116108	03/08/01	PCT				

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List of Patents and Publications for Applicant's Information Disclosure Statement				•	Applicant Lin Zhi et al.				
(37 CFR §1.98	s(b))				Filing Date Group Art Unit October 10, 2003 1625				
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Examiner	Desig.	Document	Publication		Country or		-	Trans	lation
Initial	ID	Number	Date		Patent Office	Class	Subclass	Yes	No
	DA	2004033459	04/22/04	PC	T				
	DB	2004033460	04/22/04	PC	T		·		
	DC	2004033461	04/22/04	PC	T				
	DD	9619458	06/27/96	PC	T				

	Other Documents (include Author, Title, Date, and Place of Publication)						
Examiner	Desig.						
Initial	ID	Document					
:	DE	Clemm et al., "Definition of the critical cellular components which distinguish between hormone and antihormone activated progesterone receptor," Journal of Steroid Biochemistry and Molecular Biology 53(1-6):487-495. (1995)					
	DF	Crombie et al., "Anti-progesterone effects on maternal recognition and behaviour imprinted during first pregnancy in mice," Journal of Endocrinology 147(2):331-337. (1995)					
	DG	Edwards et al., "5-Aryl-1,2-dihydro-5H-chromeno[3,4-f]quinolines as potent, orally active, nonsteroidal progesterone receptor agonists: the effect of D-ring substituents," Journal of Medicinal Chemistry. 41(3):303-310 (1998)					
	DH	Edwards et al., "Preparation, resolution, and biological evaluation of 5-aryl-1, 2-dihydro-5H-chromeno[3,4-f]quinolines: potent, orally active, nonsteroidal progesterone receptor agonists,"  Journal of Medicinal Chemistry 41(15):2779-2785 (1998)					
	DI	Hamann et al., "Nonsteroidal progesterone receptor antagonists based on a conformationally- restricted subseries of 6-aryl-1,2-dihydro-2,2,4-trimethylquinolines," Bioorganic & Medicinal Chemistry Letters 8(19):2731-2736 (1998)					
	DJ	Mais et al., "Specific interactions of progestins and anti-progestins with progesterone antibodies, plasma binding proteins and the human recombinant receptor," Journal of Steroid Biochemistry and Molecular Biology 54(1-2):63-69. (1995)					
	DK	McDonnell, D. P. and M.E. Goldman, "RU486 exerts antiestrogenic activities through a novel progesterone receptor A form-mediated mechanism," The Journal of Biological Chemistry 269(16):11945-11949. (1994)					
	DL	McDonnell et al., "Definition of the cellular mechanisms which distinguish between hormone and antihormone activated steroid receptors," Seminars in Cancer Biology, 5(5):327-336 (1994)					
	DM	McDonnell et al., "The human progesterone receptor A-form functions as a transcriptional modulator of mineralocorticoid receptor transcriptional activity," Journal of Steroid Biochemistry and Molecular Biology 48(5-6):425-432. (1994)					
	DN	Miner, J. N. and C.M. Tyree, "Drug discovery and the intracellular receptor family," Vitamins and Hormones. 62:253-280. (2001)					
	DO	Parandoosh et al., "Progesterone and oestrogen receptors in the decidualized mouse uterus and effects of different types of anti-progesterone treatment," Journal of Reproduction and Fertility 105(2):215-220. (1995)					

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Substitute For (Modified)	m PTO-1449	9 U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 18202-020001/1088	Application No. 10/684,229	
		d Publications for Applicant's n Disclosure Statement	Applicant Lin Zhi et al.		
(37 CFR §1.98	3(b)) ·		Filing Date October 10, 2003	Group Art Unit 1625	
		ocuments (include Author,	Fitle, Date, and Place o	f Publication)	
Examiner Initial	Desig. ID		Document		
	DP	Rosen et al., "Intracellular receptors a superfamilies - novel targets for small 38(25):4855-4874 (1995)	nd signal transducers and activa -molecule drug discovery," Jou	tors of transcription rnal of Medicinal Chemistry	
	DQ	Santiso-Mere, D. and D.P. McDonnel process," Chimica Oggi. 12(5-6):29-	36. (1994)	-	
	DR	Taylor et al., "Activity of progesteron system," Journal of Steroid Biochemic	stry and Molecular Biology 58(1	1):117-121 (1996)	
	DS	Vegeto et al., "Human progesterone re human progesterone receptor B functi	eceptor A form is a cell- and pro on," Molecular Endocrinology.	omoter-specific repressor of 7(10):1244-1255. (1993)	
	DT	Wagner et al., "The novel progesteror exhibit complex glucocorticoid recept dissociated antiprogestins," Endocrin	or antagonist activities: Implica	tions for the development of	
	DU	Wen et al., "The A and B isoforms of signaling pathways within target cells	the human progesterone receptor	or operate through distinct	
	DV	Zhang et al., "6-Aryl-1,4-dihydro-ben and Orally Active Nonsteroidal Proge Chemistry 45(20):4379-4382 (2002)	zo[d][1,3]oxazin- 2-ones: A No	vel Class of Potent, Selective,	
	DW	Zhang et al., "Synthesis and progester	rone receptor antagonist activities of 6-aryl benzimidazolones Medicinal Chemistry Letters 11(20):2747-2750 (2001)		
	DX	Zhi et al., "Development of progesteror f]quinoline agonist pharmacophore," [ (2003)	one receptor antagonists from 1, Bioorganic & Medicinal Chemis	2-dihydrochromeno[3,4- stry Letters. 13(12):2075-2078.	
	Zhi, et al. "Synthesis and Biological Activity of 5-Methylidine 1,2-Dihydrochromeno[3, f]quinoline Derivatives as Progesterone Receptor Modulators" Bioorganic & Medicinal Letters 13:2071-2074 (2003).				
	DZ	Zhi et al., "5-Aryl-1,2,3,4-tetrahydroc progesterone receptor agonists: effect 42(8):1466-1472 (1999)	of A-ring modification," Journa	l of Medicinal Chemistry.	
	EA	Zhi et al., "5-Benzylidene-1,2-dihydro Receptor Modulators," Journal of Med	dicinal Chemistry 46(19):4104-4	1112 (2003)	
	ЕВ	Zhi et al., "Nonsteroidal progesterone Bioorganic & Medicinal Chemistry Le	receptor antagonists based on 6	-thiophenehydroquinolines,"	

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